

REMARKS

Reconsideration and allowance are requested in view of the amendments and remarks herein.

The Examination

Claims 1, 7, and 15 were objected to because of various informalities. These informalities have been corrected according to the Examiner's suggestions.

Claims 1, 2, 3, 8, and 17 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of co-pending U.S. Patent Application Number 10/709,015, taken alone or combined with Miu et al., US Patent 6,700,174. Applicants note that, with the amendments made in this response, the Examiner may no longer reject these claims as being unpatentable under this doctrine in view of these references. Nonetheless, a Terminal Disclaimer is submitted herewith for U.S. Patent Application Number 10/709,015.

Claims 1-6, 12, 13, 15, and 16 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over US Patent 6,533,729 to Khair et al. ("Khair") in view of US Patent 6,814,705 to Kawaguchi ("Kawaguchi").

Claim 7 was rejected under 35 U.S.C. Section 103(a) as being unpatentable over Khair and Kawaguchi and further in U.S. Patent 6,027,455 to Inukai et al. ("Inukai").

Claims 8-11 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Khair in view of Kawaguchi and further in view of U.S. Patent 5,237,997 to Greubel et al. ("Greubel").

Claim 14 was rejected under 35 U.S.C. Section 103(a) as being unpatentable over Khair and Kawaguchi and further in view of U.S. Patent Number 5,297,554 to Glynn ("Glynn").

Claim 17 was rejected under 35 U.S.C. Section 103(a) as being unpatentable over Khair and Kawaguchi and further in view of U.S. Patent Number 5,752,920 to Ogura et al. ("Ogura").

Claims 19-20 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Khair in view of Kawaguchi and further in view of U.S. Patent Number 6,093,146 to Filangeri (“Filangeri”).

Amended and New Claims

In order to more clearly describe the invention, Applicants have amended claims 1, 2, 4, 6, 7, 9, and 14; deleted claims 3, 12, 13, 15-17; and added new claims 21-25. With these amendments claims 1, 2, 4-11, 14, and 18-25 are pending in this Application.

Specifically, independent claim 1 has been amended to describe a ‘hand-held device’ featuring ‘a removable, hand-held component configured to be held proximal to the patient’s skin’ during a measurement. Support for this amendment is found throughout the specification, particularly on page 5, lines 20-23 (paragraph [026]); in the description of Fig. 1 on page 12, lines 5-11 (paragraph [039]); and in the description of Figs. 2A and 2B on page 19, line 20 to page 20, line 1 (paragraph [051]). Claim 1 has also been amended to recite an optical module that generates a first set of information (e.g. an optical waveform), and an electrical sensor that generates a second set of information (e.g., an electrical signal): these components are both mounted on the hand-held component. The electrical sensor features an electrode pair that replaces ‘the flexible, thin-film pressure sensor’ recited in the original claim. Support for these amendments is also found throughout the application, particularly in Figs. 1, 2A, and 2B, on page 24, line 6 (paragraph [060]) to page 27, line 12 (paragraph [064]). Finally, claim 1 has been amended to recite a processing module that determines a blood pressure value by ‘calculat[ing] a time difference between components of the first set of information and the second set of information and compare[ing] the time difference to a mathematical model’. Support for this amendment is also found throughout the specification, particularly on page 27, line 13 (paragraph [065]) to page 23, line 20 (paragraph [072]); and in the description of Fig. 11 on page 33, line 3 (paragraph [074]) to page 36, line 11 (paragraph [079]).

New claims 21-25 include many of the limitations of the amended claims. In addition, new claims 24 and 25 include the steps of ‘wirelessly transmitting the blood pressure value to an external receiver’ and ‘transmitting the blood pressure value to an

Internet-accessible computer system'. These features are described throughout the specification, particularly on page 6, line 20 to page 8, line 23 (paragraph [030]); page 11, lines 1-4 (paragraph [036]); and page 39, line 7 to page 40, line 8 (paragraph [089]).

The Prior Art

The examiner cited the following prior art references in the Office Action mailed April 22, 2005.

Khair discloses a device that measures blood pressure using two-dimensional arrays of light sources and light detectors that monitor radiation reflecting off a surface modulated by variations in a patient's blood pressure.

Kawaguchi discloses a device that evaluates a patient's degree of arteriosclerosis featuring a 'pressing bag' that detects properties of 'pulse waves' and in response determines blood pressure.

Inukai discloses a body-worn device that estimates blood pressure and activity of an autonomic nerve system using an electrical waveform from an ECG device, an optical waveform from a conventional pulse oximeter, and a variety of parameters extracted from the waveforms.

Greubel discloses a body-worn device for measuring blood pressure that processes an optical waveform measured from an ear clip and an electrical waveform measured with a pair of ECG electrodes.

Glynn discloses a device for measuring body functions, such as blood pressure, using a 'scleral contact lens' for locating and supporting the device on a patient's eye, and an optical system that makes a spectroscopic analysis of retinal blood flow.

Filangeri discloses a physiological monitoring system that measures a patient's physiological condition, including blood pressure, and wirelessly sends this information to a base station.

Ogura discloses a cuff-based, body-worn apparatus for measuring blood pressure that measures an electrical waveform with an ECG device, an optical waveform with a pulse oximeter, and processes the characteristics of these

waveforms in the presence of an applied pressure from the cuff to determine blood pressure.

Patentability Over The Prior Art

The prior art fails to disclose the invention recited in the amended and new claims of the present Application. Specifically, Khair is silent to an optical module that detects a first set of information *combined* with an electrical sensor that detects a second set of information, as recited in the amended claims. Instead, Khair's only sensor features two-dimensional arrays of light sources and light detectors. Nor does Khair describe a processing module that receives information from an electrical sensor and optical module, and then processes this to determine blood pressure by 'calculat[ing] a time difference between components of the first set of information and the second set of information and compare[ing] the time difference to a mathematical model'. Moreover, Khair's blood pressure device is attached to the patient's wrist, whereas the claimed invention describes either a 'hand-held, removable' device (independent claims 1, 22, 23, 24) or a 'body-worn patch' (independent claim 21) that measure the information as described above.

The Examiner's secondary references fail to cure the deficiencies of Khair. For example, Inukai, Greubel, and Ogura each describe systems for monitoring blood pressure that include both optical (e.g. pulse oximeter) and electrical (e.g. ECG) sensors. But these systems are all body-worn, and in fact feature sensors that are attached to different parts of the patient's body. Indeed, the sensors described in these references –pulse oximeter and ECG– are actually *separate medical devices*. In contrast to the claimed invention, the references fail to describe a removable, hand-held system wherein both sensors are mounted on the same hand-held component, and are configured to generate readings when the hand-held component is held proximal to the patient's skin. As described in Applicants' specification, such a system has significant advantages:

The device, which can be hand-held ..., can be used for standard applications such as routine medical check-ups, surgical procedures, or measuring blood pressure at home. Or it can be used for 'telemedicine' applications based on remote monitoring since it is both cuffless and non-

invasive. In this way, the invention provides a comprehensive analysis of the patient's cardiac behavior with a simple, unobtrusive device. (paragraph [026], page 6, line 20 to page 7, line 4)

In general, the device 10 is hand-held and can measure blood pressure from any part of the patient's body. During a measurement, a medical professional places the device 10 over a body part 34 (e.g., an arm) of a patient. (paragraph [051], page 19, lines 22 to page 20, line 3)

Moreover, these references fail to disclose methods for wireless transmitting blood pressure values to an external receiver, and from there to an Internet-accessible computer system, as recited in Applicants' claims 24 and 25. The Examiner's other references, Kawaguchi, Glynn, and Filangeri, fail to even disclose both the optical and electrical sensors and methods for evaluating a time difference between signals generated by these sensors. These references are thus even further removed from the invention.

In summary, Khair, taken alone or in combination with any of the other cited prior art, fails to disclose all the limitations of the amended or new claims.

Based on the above, Applicants submit that the independent claims of the present invention, as amended, are significantly removed from Khair, either taken alone or combined with the secondary references. The dependent claims are even further removed from these references. Applicants therefore respectfully request a notice of allowance for all the pending claims of the present Application.

Respectfully Submitted,

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